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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/242,103	02/08/99	ASIUS J	0198/00047

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EXAMINER	
KOH, C	
ART UNIT	**PAPER NUMBER**
3738	5

DATE MAILED: 09/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/242,103	Applicant(s) Asius et al.
	Examiner Choon P. Koh	Group Art Unit 3738

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 1 is rejected rejected under 35 U.S.C. 102(b) as being anticipated by any one of Rosenthal et al (5,466,462) or Beisang et al (Aesth. Plast. Surg., 1992).

4. Each of Rosenthal et al ('462; abstract) or Beisang et al (1992, page 83) teaches injectable implant for human administration consisting of bioresorbable microparticles in suspension in a gel as claimed.

5. Claims 1-2, 6, 8-9, 16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ron et al (U.S. Patent No. 5,597,897).

6. Withe respect to claims 1-2, 6, 8-9, 16 and 20, Ron et al ('897) teaches injectable composition formed of bioresorbable microspheres in suspension in a gel.

7. With respect to claims 2, 6 and 16, the reference teaches polymers such as lactic acid polymers, glycolic acid polymers and lactic co-glycolic acid polymers, wherein the lactic acid polymer can be employed in its d- or l-form, or as a mixture (col. 3, lines 42-48).

8. With respect to claims 8 and 20, the reference teaches the benefit of using a gelling agent such as carboxymethylcellulose (CMC) or hydroxypropylmethylcellulose (HPMC) in the amount of 0,5-20 wt % which overlaps the range of 0.1 to 7.5% as set forth in the claims (col. 9, Example 4).

9. With respect to claim 9, Ron et al ('897) teaches a lyophilized, i.e. freeze-dried, implant product to which is added water for injection as set forth in the claim (col. 9, lines 23-28).

10. Claims 5, 7, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al (U.S. Patent No. 5,597,897).

11. Ron et al ('897) teaches the molecular weight of the polymer ranging from about 1,000 to 100,000, when the polymeric particles are formed from a copolymer of lactic acid and glycolic acid and further teaches that the higher the molecular weight the slower the biodegradation (col. 3, lines 54-58).

12. With respect to claims 5, 7, 13 and 19, even though Ron et al ('897) does not teach specific period during which the polymeric particles are bioabsorbable or the specific range of a molecular mass between 70,000 and 175,000 Dalton, an intrinsic viscosity of between 3 and 4 dl/g , the percentage of residual monomer and the percentage of residual solvents as set forth in the claim, based on the correlation between the molecular mass and the rate of bioresorbability of the polymers taught by Ron et al ('897), it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the polymers or copolymers based on the molecular mass to obtain the polymeric microparticles in the implant that are bioresorbable within desired period, e.g. within a period of 1 year to 3 years as claimed.

13. Although Ron et al do not characterize their polymer particles in terms of viscosity and the percentage of residual monomer and solvents as set forth in claim 7, viscosity would be an inherent property of the polymers based on its molecular mass and would vary with the molecular weight of the polylactic acid used. Furthermore, because it is desirable to remove from a polymeric product most of residual monomers and solvents to obtain a purest product possible, the percentage of residual monomer and solvents as set forth in the claim would be conventional.

14. Claims 3-4, 10-12, 14-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al (U.S. Patent No. 5,597,897) as applied to claims 1-2 above, and further in view of any one of Ersek et al (5,258,028) or Wallace et al (EP 0 251 695).

15. With respect to claims 3-4, 10-12, 14-15 and 17-18, while Ron et al ('897) teaches the invention substantially as claimed, the reference does not teach specific size of the microspheres or microparticles as set forth in claims 4, 11-12, 15 and 18, or the specific range of concentration of microspheres or microparticles in the gel as set forth in claims 3, 10, 14 and 17.

16. Ersek et al ('028) teaches an injectable implant composition which includes polymer microparticles suspended in a gel where the particles having an average diameter of 80 microns when injected showed no migration from the injection site (col. 8, lines 50-58).

17. Wallace et al ('695) teaches injectable aqueous suspension of biomaterials, wherein the biomaterials are particulate, i.e. particles, and further teaches that the particle size of the biomaterial will depend upon the gauge of the needle that is to be used to inject it into the body and the maximum particle size that can be extruded through such needles depend on various factors, including the particle maximum dimension, particle rigidity, the viscoelastic properties of the suspending fluid (page 3, lines 20-30).

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to optimize the particle size of the microparticles of Ron et al to the size desirable and effective for desired effect when used as an injectable implant at a particular site of implantation. As to the amount of microparticles in the gel, the concentration would depend on desired effect at the site of implantation.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Scopelianos et al (5,599,852) teaches injectable, bioabsorbable microdispersions comprising a fluid carrier that is liquid polymers and a particulate material, wherein unreacted monomer is removed and further teach various polymers having different inherent viscosity.

Costantino et al (1994) teaches various factors that affect biocompatibility of the implantable biomaterials, including particle size (pages 3, 9, 11).

Ersek et al (Aesth. Plast. Surg., 1992) teaches various characteristics desirable in a soft tissue implant, including particle size which should be large enough to prevent migration after implantation and the size small ineough to allow implantation by minimally invasive blunt cannula procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ms. Choon P. Koh whose telephone number is (703) 305-1232. The examiner can normally be reached on Monday - Thursday from 6:30 AM to 4:00 PM. The examiner can also reached on alternate Friday from 6:30 AM to 3:00 PM .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 (formal) and (703) 308-2708 (informal) .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Choon P. Koh

Choon P. Koh
September 8, 2000

David J. Isabella
Primary Examiner